

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Pei KAN Confirmation No: 5546
Appl. No. : 10/748,192
Filed : December 31, 2003
Title : THERMOGELLING EMULSIONS FOR SUSTAINED
RELEASE OF BIOACTIVE SUBSTANCE

TC/A.U. : 1612
Examiner : N. Holloman

Docket No.: : KANP3002/REF
Customer No: : 23364

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants are in receipt of the Official Action dated January 20, 2010 and its contents have been carefully considered. Applicants request an interview with the Examiner to discuss the outstanding rejection, the present response and the necessary amendments or steps to place this application in early condition for allowance.

Applicants have carefully considered the rejection of claims 1-21, 23, and 24 under 35 U.S.C. 103, but is most respectfully traversed based on the following. Applicants most respectfully submit that one of ordinary skill in the art would appreciate that D1 (US 6,632,457) tried to propose a two-phase hydrogel system to control the release rate. During preparation, D1 used oil-in-water-in oil with macromer polymerized in the outside water phase to form the system. Basically, the oil-in-water-in-oil double emulsions are easily broken, the oil phase inside the water phase during emulsification.

At the same time, some hydrophobic substance may partition to the outside oil phase or accumulated on the outside surfaces of hydrogel microspheres once the hydrogel microspheres become solid through polymerization. As a result, the outside surface-associated hydrophobic substance may release very quickly and result in a burst effect.

Also, when the polymer proposed by D2 (US 6,841,617) or D3 (US 6,592,899) and the other available thermal sensitive hydrogels was used alone, the drug delivery

system showed a burst effect due to high percentage of water content in the solidified depot. Burst effect is well known as a disadvantage of this kind of delivery system. However, as noted in the present specification at page 19, the time release was extended by three fold and the burst release was also reduced. The unique combination of properties exhibited by the systems of the present invention are clearly set forth in the specification and these are not suggested by the prior art. The test data in the specification is evidence of the patentability of the claimed subject matter which must be taken into consideration in evaluating the patentability of the claimed subject matter. Rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995), by counsel, *In re Chu*, 66 F.3d 292, 299, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995).

Taken together, the delivery systems based D1, D2 and D3 alone cannot avoid the burst effect. It can not theoretically be anticipated that combining two delivery systems with burst releasing can improve burst effect. However, in the present invention, we conducted a series of experiments and found the unexpected improvement to reduce burst effect by thermal gelling emulsion system.

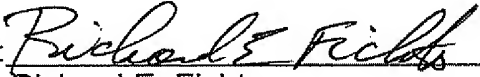
In addition, D1 system cannot be applied for the other thermal gelling hydrogel system (gelling temperature close to physiological temperature), as Applicants explained in the previous response, herein incorporated by reference. Basically, the concept of D1 is totally unable to be combined with thermogelling hydrogel to constitute the similar system as presently claimed. Accordingly, it is most respectfully requested that this rejection be withdrawn as claim 22 is also clearly patentable. All of the claims are patentable over the prior art applied in each rejection. Each rejection should be withdrawn.

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Amendment dated: April 20, 2010
Reply to OA of: January 20, 2010

In view of the foregoing election, examination of the elected invention on the merits and consideration of a reasonable number of claims with an allowable generic claim is in order and most respectfully requested as is the right of rejoinder.

Respectfully submitted,

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April 20, 2010